

WACKER

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VIA ELECTRONIC AND EXPRESS MAIL

March 31, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

RE: Wacker Chemical Corporation and Wacker Specialties Comments on FDA's Proposed Regulation Titled Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. [Docket No. 02N-0278]

Dear Sir or Madam:

Wacker Chemical Corporation and Wacker Specialties of Adrian, Michigan hereby respectfully submit these comments with regard to the Proposed Regulation on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 published in the Federal Register on February 3, 2003 (68 Fed. Reg. 5428).

Wacker Chemical Corporation and Wacker Specialties assert that the prior notice requirement with respect to materials defined as food contact materials or indirect food additives is contrary to Congressional intent. FDA has proposed to include suppliers of materials which do not contain food within the reach of the regulations by using the definition of "food" found in Section 201 (f) of the FFDCA which defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article". Section 201 of the FFDCA defines a food additive to include "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly in its becoming a component or otherwise affecting the characteristics of any food". This definition covers all the food additive substances listed in 21 CFR 170-199. Furthermore FDA's definition of food even extends to substances that migrate into food from food packaging and other articles that contact food.

¹ Wacker Chemical Corporation is the United States based headquarters for Wacker Silicones and Wacker Ceramics business divisions of Wacker-Chemie, GmbH. Wacker Silicones manufactures silicone fluids, rubbers and resins; silanes; and fumed silica's. Wacker Ceramics manufactures advanced ceramics, boron compounds, functional coatings, and microporous insulation materials. Wacker Specialties imports redispersible powders, solid resins, polyvinyl butyrals, specialty chemicals, catalysts and manufactures biotechnology products.

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This broad definition of "food" requires prior notice for materials that may be used for the manufacture of indirect food contact articles such as conveyor belts, oven gaskets, coatings on metal substrates, adhesives, antifoam agents used in food processing, components of polyolefin films, colorants used in polymers, rubber articles, release coatings, etc. This would impose a significant burden on many companies including the Wacker companies that do not now file entry information with FDA because most of the materials with indirect food contact are also primarily used as industrial non food contact materials. In most cases it is impossible to know if a Wacker material will be used to mold parts for an automobile gasket or for an oven gasket. In addition, at the time of import these materials are not used in food or are they edible foods nor are they in contact with food.

Such a broad definition in the proposed regulation with respect to food contact materials is contrary to the intent of Congress, which was to protect "food for consumption in the United States". A clarification needs to be made to the regulation to define food consumption as referring to edible food and not food contact materials, indirect food additives or substances which might migrate to food. There was no Congressional intent to require advance notice of importation of food contact materials not yet in contact with food.

Additionally including food contact materials, indirect food additives or substances, which might migrate to food in the regulation will impose burdens on the industry that are disproportionate to any minimal risk and will provide no protection against terrorism. Food contact materials have not been related to any occurrences of food borne illness from accidental or intentional contamination of edible food. Indirect food contact materials such as silicone elastomers, resins, various polymers, antifoams and pulp and paper treatment chemicals to name a few, are only used in indirect contact with food and are in most cases imported as industrial chemical products that may have a indirect food contact use once they are sold within the United States. They are not imported with the sole purpose of being consumed as edible food in the United States. Nor are they in contact with food when imported.

In conclusion, the requirement on industry to provide prior notice of importation of "food" should not be extended to any food contact materials, indirect food additives or substances which might migrate to food which do not already contain food or are in contact with edible food. FDA's proposed regulation is contrary to Congressional intent and will not provide protection against terrorism.

Wacker Chemical Corporation and Wacker Specialties appreciates the opportunity to provide comments on this proposed regulation.

Sincerely,



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A handwritten signature in black ink that reads "Sharronn E. Etter". The signature is written in a cursive style with a large, stylized 'S' and 'E'.

Sharronn E. Etter
Director, Regulatory Affairs and Product Safety